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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,849	05/23/2001	Jerome O. Cantor	C35795/125237	1932

83369 7590 01/22/2010

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EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
01/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/863,849	CANTOR ET AL.	
	Examiner	Art Unit	
	MICHAEL C. HENRY	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-33,37-41 and 43-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-33,37-41 and 43-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/26/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 10/26/09.

The amendment filed 10/26/09 affects the application, 09/863,849 as follows: Applicant's arguments have overcome the rejection made under 35 U.S.C. 103(a) with respect to the use of the Sanders et al. (S.T.P. Pharma Sciences (1997), 7(4), 300-306) reference in the prior office action mailed 06/23/09. However, a new ground(s) rejection is set forth herein below.

The responsive to applicants' arguments is contained herein below

Claims 31-33, 37-41, 43-48 are pending in application

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 38 recites the phrase "chemically modified". However, the claim is indefinite because it is unclear what how said glycosaminoglycan of the mixture is chemically modified or what moiety, substituent, compound or substance results from such chemical modification. Claim 44 recites the phrase "wherein the glycosaminoglycan is dextran. However, the claim is unclear and indefinite since dextran is not a glycosaminoglycan.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 31-33, 37-41, 43-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cantor (US 5,633,003) in view of Sackner (US 4, 679,555).

In claim 31, applicant claims "A system for pulmonary delivery to a mammal of an inhalable aerosol mist of a glycosaminoglycan in an amount effective to coat elastic fibers of the lung to protect the fibers from injury by an elastase, comprising:

a mixture comprising a glycosaminoglycan having a molecular weight of between about 50,000 and 1.5 x 10^6 Daltons at a concentration of less than about 5.0 mg/ml (w/v) of glycosaminoglycan, and a breathable fluorocarbon propellant; a canister adapted to contain said mixture under pressure; a valve connected to said canister for regulating delivery of said mixture; and a nozzle interconnected with said valve for transforming said mixture under pressure into the inhalable aerosol mist when said valve is actuated." Dependent claim 32 is drawn to said composition or system comprising the glycosaminoglycan in the aerosol mist is of specific median mass distribution sizes. Claim 33 and 37 are drawn to said system or composition wherein the said mixture further comprises a drug and specific drugs. Claims 37-40, 42, 43, 45-48 are drawn to said system or composition wherein the glycosaminoglycan of the mixture is chemically modified, wherein the said mixture further comprises a drug and specific drugs, wherein the glycosaminoglycan are specific glycosaminoglycan and are of specific molecular

weights. Claim 41 is drawn to said system wherein a drug is conjugated to the glycosaminoglycan.

Cantor discloses a system for delivering a glycosaminoglycan or polysaccharide formulation to a respiratory tract of a mammal, comprising: a mixture comprising a polysaccharide or glycosaminoglycan (hyaluronic acid), that can be delivered via a route aerosol inhalation by a nebulizer (see col. 3, METHODS, lines 46 to col. 4, line 45; also, see abstract). In addition, Cantor uses the same method of delivery (aerosol inhalation) for the same purpose (i.e., treating respiratory disorders) comprising a glycosaminoglycan or polysaccharide. Furthermore, it should be noted that the nebulizer contains the said canister, valve and nozzle, claimed by applicant. Also, Cantor discloses that the hyaluronic acid used may be derived from bovine sources, rooster comb, human umbilical cord, or streptoccus zoepidicus (see col. 3, lines 13-18). This implies that hyaluronic acid of different molecular weights can be used since the said sources of hyaluronic acid produces hyaluronic acid of different molecular weight. In fact, the hyaluronic acid suggested by Cantor are naturally occurring hyaluronic acid (i.e., hyaluronic acid from bovine sources, rooster comb, human umbilical cord, or streptoccus zoepidicus (see col. 3, lines 13-18) which are known to have molecular weight of 50,000-13,000,000 daltons (for example, see US 4,746,504: col. 4, lines 44-49). It should be noted that this molecular weight range of hyaluronic acid encompasses the molecular weight range of the hyaluronic acid claimed by applicant.

The difference between applicants' claimed composition and the composition of Cantor is that Cantor does not disclose the concentration, molecular weight of the polysaccharide or glycosaminoglycan and Cantor does not use a drug or propellant. However, Cantor suggests that

hyaluronic acid from different sources (i.e., hyaluronic acid from bovine sources, rooster comb, human umbilical cord, or streptoccus zoepidicus (see col. 3, lines 13-18)) which are known to have different molecular weights can be used and Cantor disclose that the effective daily amount of hyaluronic acid is from about 10 μg/kg to about 1 mg/kg of body weight (see abstract and col. 2, lines 47-67). This suggest that the concentration can encompass the concentration claimed by applicant since the mass and thus the concentration to be prepared depends on the body weight (kg) of the recipient and especially since Cantor exemplifies a concentration (1.0 mg/0.2ml or 5.0 mg/ml) that is substantially close to applicant's claimed concentration.

Sackner discloses that a low boiling point propellant which is preferably used in combination with an inhalation device is capable of improving efficiency with respect to the amount of heparin (a glycosaminoglycan) reaching the lungs of a patient (see abstract). Furthermore, Sackner disclose that useful propellants include various types of hydrocarbons, fluorocarbons and chlorocarbons (see col.4, lines 17-22) and that the propellants can be chlorofluoralkane (see claim 5 and claim 9).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared the composition (an inhalant aerosol formulation) of Cantor comprising different concentrations, molecular weights or particle size of the polysaccharide or glycosaminoglycan with a fluorocarbon propellant to be used as an inhalant aerosol formulation for treating respiratory conditions or disorders, depending on factors such as the severity of the respiratory disorder or the type, age and weight of subject treated, since Cantor suggests that different molecular weights of hyaluronic acid (polysaccharide) can be used

and Sackner discloses that a propellant such as a chlorofluoralkane improve the efficiency of delivered of heparin, a glycosaminoglycan, from metered dose inhalers to a patient's lungs.

One having ordinary skill in the art would have been motivated, to prepare the composition (an inhalant aerosol formulation) of Cantor comprising different concentrations, molecular weights or particle size of the polysaccharide or glycosaminoglycan with a fluorocarbon propellant to be used as an inhalant aerosol formulation for treating respiratory conditions or disorders, depending on factors such as the severity of the respiratory disorder or the type, age and weight of subject treated, since Cantor suggests that different molecular weights of hyaluronic acid (polysaccharide) can be used and Sackner discloses that a propellant such as a chlorofluoralkane improve the efficiency of delivered of heparin,a glycosaminoglycan, from metered dose inhalers to a patient's lungs. It should be noted that it is obvious to combine other drugs such as terbutaline and Beclomethasone (which are often used for asthma treatment) with the hyaluronic acid or glycosaminoglycan since they have the same utility. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980). It should be noted that it is obvious to use other polysaccharides including polysaccharides that are conjugated to a drug since both Cantor disclose the use of polysaccharides in general.

Response to Arguments

Applicant's arguments with respect to claims 31-33, 37-41 and 43-48 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry
January 16, 2010.

/Shaojia Anna Jiang/
Supervisory Patent Examiner
Art Unit 1623